



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,967	03/12/2007	Jef Fensholdt	3893-0250PUS1	8915
2292 7590 02/25/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
SOLOLA, TAOFTQ A				
ART UNIT		PAPER NUMBER		
1625				
NOTIFICATION DATE		DELIVERY MODE		
02/25/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/580,967

Applicant(s)

FENSHOLDT ET AL.

Examiner

Taofiq A. Solola

Art Unit

1625

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 5-21, 23, 25-27, 40 and 44 is/are pending in the application.
- 4a) Of the above claim(s) 40 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5-21, 23 and 25-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/31/06, 3/19/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claims 1, 3, 5-21, 23, 25-27, 40, 44, are pending in this application.

Claims 40, 44, are drawn to non-elected inventions.

Claims 2, 4, 22, 24, 28-39, 41-43, 45-49, are deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5-21, 23, 25, 27, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The extensive negative limitations at the end of claim 1 render claims 1, 3, 5-21, 23, 25, 27 indefinite and unpatentable. It does not comply with 35 USC 112. "It is [an] attempt to claim invention by excluding what applicants did not invent rather than by particularly and distinctly pointing out what they did invent." *In re Schechter*, 98 USPQ 144 (CCPA, 1953), *In re Rose*, 86 USPQ 77 (CCPA, 1950). Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5-6, 8, 10-11, 13-21, 23, 25-26, are rejected under 35 U.S.C. 102(b) as being anticipated by Beilstein Registry, XP-002319951 (7/11/89); XP-002319952 (6/29/89); and XP-002319954 (2/15/90); individually.

The prior arts disclose compound having RN 2826119, 2186299 and compound 3461601 respectively.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 5-21, 23, 25-27, are rejected under 35 U.S.C. 103(a) as being unpatentable over Beilstein Registry, XP-002319951 (7/11/89); Bridges et al., WO 00/40235; Barrett et al., WO 99/01426; Barrett et al., WO 03/062191; Barrett et al., WO 02/06213; Barrett et al., WO 03/62189; and Dudley et al., WO 00/35436; individually in view of King, Med Chem: Principle and Practice (1994), p. 206-208.

Applicant claims compounds of formula I and composition thereof useful for cancer, inflammation, asthma, arthritis, etc.

Determination of the scope and content of the prior art (MPEP 2141.01)

XP-002319951 teaches the compound cited above.

WO 00/40235 teaches similar compounds and composition thereof for inflammation and asthma (see pp. 5-22, 37-54, 66-74).

WO 99/01426 teaches similar compounds and composition thereof useful for cancer (see pp. 57-10, examples 1-102 on pp. 21-33 and the claims.

WO 03/062191 teaches similar compounds and composition thereof for inflammation and cancers (see formula I, page 3, and pp. 36-43).

WO 02/06213 teaches similar compounds and composition thereof for inflammation and cancers (see the examples, especially formula II-V, pp. 73-74).

WO 03/62189 teaches similar compounds and composition thereof for inflammation and cancers (see formula I, page 3, and the examples on pp. 21-24, 27-45).

WO 00/35436 teaches similar compounds and composition thereof for arthritis (see examples on pp. 5-14, 16-24).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant invention and that of the prior arts is that the instant compounds are adjacent homologs (X is alkyl) of the compounds by the prior art.

Also applicant replaced the ring(s) in the prior arts' compounds with their bioisosteric equivalents ring(s).

Finding of prima facie obviousness---rational and motivation (MPEP 2142.2413)

When the difference between compounds is the length of a carbon chain such are adjacent homologs. However, adjacent homologs are prima facie obvious. *In re Henze*, 85 USPQ 261 (1950).

Also, King teaches that replacement of bioisosteric equivalent rings in a compound is expected to produce compounds having similar biological activity

(bioisosterism). See ring equivalents, page 208. See also, *Ex parte Engelhardt*, 208 USPQ 343 (Bd. Pat. App. & Int., 1980); *In re Merck*, 231 USPQ 375 (Fed. Cir. 1986).

Therefore, the instant invention is *prima facie* obvious from the teachings of the prior arts. One of ordinary skill in the art would have known to claim adjacent homologs and/or bioisosteric equivalents of the compounds by the prior arts at the time the invention was made. The motivation is from knowing that adjacent homologs and/or bioisosteric equivalents would have similar biochemical properties.

Alternatively, under the recent decision in *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727,-----, 82 USPQ2d 1385 (2007), obvious to try is now appropriate test of motivation.

When there is motivation

to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under [35 USC] 103.

KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727,-----, 82 USPQ2d 1385, 1397 (2007).

A person of ordinary skill would have known to claim adjacent homologs and/or bioisosteric equivalents at the time the invention was made. The limited and available options are 1) try bioisosteric equivalent rings as suggested by King and/or 2) add carbon chain at position X to avoid the prior arts. These are identifiable and finite options. There is anticipated success because each of these modifications is routinely

practiced by drug development chemists. Therefore, any of the modifications is an obvious selection available for the preference of an artisan.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

/Taofiq A. Solola/

Primary Examiner, 1625

February 20, 2010

